K093683.

INSTRUMENTARIUM

510(k) Summary

OCT - 6 2010

Date:

April 29., 2010

The name of the 510(k) owner:

Instrumentarium Dental, PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, Finland

Tel: +358 10 270 2000
Fax: +358 9 851 4048

Contact person: Mr. Matti Tulikoura, Tel +358 400 609 507

United States Sales Representative (U.S. Designated agent):

INSTRUMENTARIUM DENTAL INC.
1245 W. Canal Street, Milwaukee,
Wisconsin 53233, USA

Tel: +1 414 747 1030, 800 558 6120
Fax: +1 414 481 8665

Contact Person: Mr. Frank Kashinski, Tel +1 414 747 6315

Trade name:

Orthopantomograph® OP300

Common name:

Dental panoramic, cephalometric and cone beam computed tomography x-ray device

Classification name:

System, x-ray, extraoral source, digital (21 CFR 872.1800, product code MUH)

Predicate device:

Planmeca Promax 3D (K060328), SCANORA® 3D (K073350) and Veraviewepocs 3D (K073696).

Description:

Orthopantomograph® OP300 is an extraoral source dental x-ray device, which produces conventional digital 2D panoramic, cephalometric and TMJ x-ray images as well as digital x-ray projection images taken during cone beam rotations around a patient's head. The projection images are reconstructed to be viewed in 3D by a 3D viewing software. The name Orthopantomograph® OP300 is used when the device can produce panoramic, TMJ and optionally 3D images. The name Orthoceph® OC300 is used when the cephalometric option for cephalometric x-ray images is added to the device. Furthermore, the device can be equipped with the Volumetric Tomography device (K063773).

INSTRUMENTARIUM

Intended use:

The Orthopantomograph® OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view. The device must only be operated and used by dentists and other legally qualified professionals.

Technological characteristics:

The Orthopantomograph® OP300 is similar to the predicate devices Planmeca Promax 3D & Soredex Scanora 3D and otherwise similar to the Morita Veraviewepocs 3D predicate device by offering options for conventional cephalometric x-ray images and cone beam 3D images using pulsing and continuous power mode.

Substantial Equivalence:

We consider Orthopantomograph® OP300 is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Matti Tulikoura
Regulatory Manager
Instrumentarium Dental, PaloDEx Group OY
Nahkelantie 160, Tuusula 04300
FINLAND

OCT 06 2010

Re: K093683
Trade/Device Name: Orthopantomograph® OP300
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 3, 2010
Received: September 8, 2010

Dear Mr. Tulikoura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INSTRUMENTARIUM

Indications for Use

510(k) Number (if known): K093683

Device Name: Orthopantomograph® OP300

Indications for Use:

The Orthopantomograph® OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view. The device must only be operated and used by dentists and other legally qualified professionals.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

for David G. Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093683

Instrumentarium Dental
Street address: Nahkelantie 160, 04300 Tuusula Finland
Postal address: P.O. Box 20, FI-04301 Tuusula, Finland
Tel. +358 45 7882 2000
Fax +358 45 7882 2506

Bank SWIFT Nordea Bank NDEAFIHH
Account: FI9015963000046864

PaloDEx Group Oy, Tuusula, FINLAND
Business ID 1981046-8
VAT FI19810468